K120715
PAGE 1 of 2

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

zimmer

AUG 10 2012

510(k) Summary

Sponsor:	Zimmer, GmbH SulzerAllee 8 Winterthur, Switzerland CH-8404
Contact Person:	Stephen H. McKelvey Senior Project Manager, Trauma Regulatory Affairs Telephone: (574) 372-4944 Fax: (574) 371-8760
Date:	August 9, 2012
Trade Name:	*Zimmer Natural Nail* System Cephalomedullary Femoral Nail - Asia Short
Common Name:	Intramedullary Fixation Rod
Classification Names And References:	Intramedullary Fixation Rod ,.product code HSB (21 CFR section 888.3020)
Predicate Devices:	*Zimmer Natural Nail* System Cephalomedullary Femoral Nails, Manufactured by Zimmer, K091566, cleared October 28, 2009 and Intramedullary Nail System, Manufactured by Zimmer, K965098, cleared February 28, 1997.
Device Description:	The *Zimmer Natural Nail* System Cephalomedullary Femoral Nail - Asia Short are temporary fixation intramedullary nails designed for fracture fixation and stabilization of the femur. The nails are available in a variety of lengths and diameters to meet assorted anatomical needs. Each of the intramedullary nails is secured by a series of screws that pass through holes manufactured into the proximal and distal sections of each nail. Nail caps are available to prevent tissue ingrowth into nail threads and increase the length of the nail if desired. These devices are made from Ti-6Al-4V alloy and are provided sterile.
Intended Use:	The *Zimmer Natural Nail* System is intended for temporary fracture fixation and stabilization of the bone.

Indications for use of the Cephalomedullary nails include:

- Compound and simple shaft fractures
- Proximal, metaphyseal and distal shaft fractures
- Segmental fractures
- Comminuted fractures
- Fractures involving osteopenic and osteoporotic bone
- Pathological fractures
- Fractures with bone loss
- Pseudoarthrosis, non-union, mal-union and delayed union
- Periprosthetic fractures
- Surgically created defects such as osteotomies
- Intertrochanteric and subtrochanteric fractures

Comparison to Predicate Device:

The subject *Zimmer Natural Nail* System Cephalomedullary Femoral Nail - Asia Short have three modifications when compared to the predicate *Zimmer Natural Nail* System Cephalomedullary Femoral Nails; 1) A 9.3 mm diameter line extension was added to the nail scope, 2) the tip design of the subject nails was changed by moving the distal locking holes 20 mm distally and reducing the length of the tip slots/flutes, and 3) the distal locking hole angle was changed from 8.5 degrees to 7.0 degrees to accommodate a minor change in the associated targeting guide instrument. All other design and processing parameters (e.g., other dimensions, materials, sterilization, packaging, etc.) are identical to the predicate devices.

Performance Data (Nonclinical And/or Clinical):

Non-Clinical Performance and Conclusions:

Testing/Analysis performed included; A fatigue strength evaluation of the proximal segment of the subject nail and a distal tip evaluation of the tensile stress under cantilever loading to confirm that the modifications would not affect safety and effectiveness.

The results of non-clinical (lab) performance testing demonstrate that the subject devices are safe and effective and substantially equivalent to the predicate devices.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUG 10 2012

Zimmer, GmbH.
% Mr. Stephen H. McKelvey, MA, RAC
Zimmer, Inc.
345 East Main St.
Warsaw, IN 46580

Re: K120715
Trade/Device Name: Zimmer Natural Nail System - Cephalomedullary Femoral Nail - Asia Short
Regulation Number: 21 CFR 888.3020
Regulation Name: Rod, fixation, intramedullary and accessories
Regulatory Class: II
Product Code: HSB
Dated: July 10, 2012
Received: July 12, 2012

Dear Mr. McKelvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120715

Indications for Use

510(k) Number (if known):

Device Name:

Zimmer Natural Nail System Cephalomedullary Femoral Nail - Asia Short

Indications for Use:

The *Zimmer Natural Nail* System is intended for temporary fracture fixation and stabilization of the bone.

Indications for use of the Cephalomedullary nails include:
- Compound and simple shaft fractures
- Proximal, metaphyseal and distal shaft fractures
- Segmental fractures
- Comminuted fractures
- Fractures involving osteopenic and osteoporotic bone
- Pathological fractures
- Fractures with bone loss
- Pseudoarthrosis, non-union, mal-union and delayed union
- Periprosthetic fractures
- Surgically created defects such as osteotomies
- Intertrochanteric and subtrochanteric fractures

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120715